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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,011	10/25/1999	MICHAEL SIMONS	BIS-043/CIP	1306

7590 01/19/2005

DAVID PRASHKER PC
P O BOX 5387
MAGNOLIA, MA 01930

EXAMINER	
TELLER, ROY R	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/426,011	SIMONS ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment, received 11/5/04, in which applicant amended claim 11. The applicant has requested an explanation from the examiner regarding the restriction requirement of 4/7/03. The restriction requirement of 4/7/03 on page 4, second paragraph was not an election of species but rather a restriction to one patentably distinct sequence. The family of PR-39 derived oligopeptides was properly restricted to one invention chosen by applicant so the examiner could examine the chosen invention.

Claims 11 and 12 are pending.

Claim Rejections - 35 USC § 112

The rejection under 35 U.S.C. 112, first paragraph of claims 11 and 12 is maintained for reasons of record which are restated below..

Claims 11and 12 are/stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:7; peptide PR-11(experiment # 6, page 46 of the instant specification); who individually causes a selective inhibition of proteasome-mediated degradation for at least one identifiable peptide in-situ after introduction intracellularly to a viable cell, does not reasonably provide enablement for a family of PR-39 derived oligopeptides whose members individually cause a selective inhibition of proteasome-mediated degradation for at least one indentifiable peptide in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family: being a peptide ranging from about 8 to

about 25 amino acids residues in length; having a N-terminal amino acid residue sequence which begins with Arg-Arg-Arg; being a peptide which is devoid of the amino acid residue sequences Pro-Pro-X-X-Pro-Pro-X-X-Pro and Pro-Pro-X-X-X-Pro_pro-X-X-Pro where X is any amino acid; being able to interact in-situ with such proteasomes as are present within the cytoplasm of the cell; and being able to alter markedly the proteolytic degradation of at least one identifiable peptide mediated by said interacting proteasomes such that an increased expression of said identifiable peptide occurs in-situ. In view of the above, those skilled in the art are unlikely to accept the data as being correlatable to SEQ ID NO:3, a 15 amino acid residue and a family of PR-39 derived oligopeptides whose members individually cause a selective inhibition of proteasome-mediated degradation for at least one indentifiable peptide in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family: being a peptide ranging from about 8 to about 25 amino acids residues in length; having a N-terminal amino acid residue sequence which begins with Arg-Arg-Arg; being a peptide which is devoid of the amino acid residue sequences Pro-Pro-X-X-Pro-Pro-X-X-Pro and Pro-Pro-X-X-X-Pro_pro-X-X-Pro where X is any amino acid; being able to interact in-situ with such proteasomes as are present within the cytoplasm of the cell; and being able to alter markedly the proteolytic degradation of at least one identifiable peptide mediated by said interacting proteasomes such that an increased expression of said identifiable peptide occurs in-situ. Therefore, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success.

Applicant's arguments have been carefully considered but were not found persuasive.

Applicant contends that the examiner has: 1) failed to present a *prima facie* case,

2) conducted an evaluation which does not conform to the correct and proper objective legal standards regarding enablement, and 3) failed to appreciate properly the totality of factual content disclosed in the instant specification. However, the examiner contends that 1) a *prima facie* case has been presented, 2) an evaluation based upon the WANDS factors for scope of enablement has been performed, and 3) the totality of the disclosed instant specification has been considered. Based upon the teachings, or lack thereof, included in the instant specification and claims the examiner contends that the instant specification, while being enabling for SEQ ID NO:7; peptide PR-11(experiment # 6, page 46 of the instant specification); who individually causes a selective inhibition of proteasome-mediated degradation for at least one identifiable peptide in-situ after introduction intracellularly to a viable cell, does not reasonably provide enablement for a family of PR-39 derived oligopeptides whose members individually cause a selective inhibition of proteasome-mediated degradation for at least one indentifiable peptide in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family: being a peptide ranging from about 8 to about 25 amino acids residues in length; having a N-terminal amino acid residue sequence which begins with Arg-Arg-Arg; being a peptide which is devoid of the amino acid residue sequences Pro-Pro-X-X-Pro-Pro-X-X-Pro and Pro-Pro-X-X-X-Pro_pro-X-X-Pro where X is any amino acid; being able to interact in-situ with such proteasomes as are present within the cytoplasm of the cell; and being able to alter markedly the proteolytic degradation of at least one identifiable peptide mediated by said interacting proteasomes such that an increased expression of said identifiable peptide occurs in-situ.

Claim Rejections - 35 USC § 103

The rejection under 35 U.S.C. 103(a) of claims 11 and 12 is maintained for reasons of record which are restated below.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross (USPN 6,133,233).

The instant invention is drawn to disclose a PR-39 derived oligopeptide family whose members individually cause a selective inhibition of proteasome-mediated degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 26 amino acids residues and having an N-terminal sequence of Arg-Arg-Arg. The instant invention provides an in-situ stimulation of angiogenesis. By definition, therefore, both in-vivo and in-vitro circumstances of use and applications are envisioned and expected (see, e.g., for example page 8)

Ross teaches an in vivo method of reducing reperfusion injury in a mammal which comprise the steps of administering into the mammal's bloodstream an effective amount of proline/arginine rich peptide. Ross discloses SEQ ID NO:4, a 14 amino acid peptide which is a 92% query match with SEQ ID NO:3 of the instant application (see, e.g., for example, abstract, column 2, column 9, and claim 2).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Applicant's arguments have been carefully considered but were not found persuasive.

Applicant contends that there are many factual differences and substantive distinctions between the instantly claimed invention and the Ross '233 patent reference. However, the examiner contends that the Ross reference discloses a PR-39 peptide, SEQ ID NO:4, a 14 amino acid peptide which is a 92% query match with SEQ ID NO:3 of the instant application (see, e.g., for example, abstract, column 2, column 9, and claim 2).

Conclusion

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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1/14/05
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CHRISTOPHER R. TATE
PRIMARY EXAMINER